# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT	)	
LITIGATION	)	Civil Action No. 05-356-KAJ
	)	(consolidated)
	)	

# STIPULATION REGARDING IVAX

IT IS HEREBY STIPULATED, CONSENTED, AND AGREED TO by and between the parties hereto as follows:

- 1. Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc. and Defendants Alphapharm Pty Ltd. ("Alphapharm"), Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (collectively, "Barr"), and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva") are parties to this consolidated patent infringement case (the "Parties") involving Plaintiffs' U.S. Patent No. 4,663,318 ("the '318 patent").
- 2. The Parties stipulate that Ivax Pharmaceuticals, Inc. has filed an Abbreviated New Drug Applications ("ANDA") seeking approval from the Food & Drug Administration to engage in the commercial manufacture, use, marketing, and/or sale of a generic version of a galantamine hydrobromide product for the treatment of Alzheimer's disease.
- 3. The Parties further stipulate that IVAX filed a certification with its ANDAs regarding the '318 patent, as required by 21 U.S.C. § 355(j)(2)(A)(vii).
- 4. The Parties further stipulate that the IVAX's certification regarding the '318 patent was pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certifications"), which stated that in the opinion of IVAX and to the best of IVAX's knowledge, the '318 patent will expire on December 14, 2008. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III).

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